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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,674	11/13/2003	Ken Y. Lin	STAN-276	9855

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EXAMINER	
VENCI, DAVID J	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 08/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/713,674	LIN ET AL.	
	Examiner	Art Unit	
	David J. Venci	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *June 8, 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *10-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 15-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-18* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

Examiner acknowledges Applicants' reply, filed June 8, 2005, which amended claims 1 and 5-6, and added new claims 15-18.

Currently, claims 1-9 and 15-18 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

Claims 1-8 and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Balint & Cooke (WO 98/49199) in view of Duerksen & Wilkinson, 160 ANAL. BIOCHEM. 444 (1987).

Balint & Cooke teach a method of detecting ADMA (see Abstract) in a sample comprising ADMA, SDMA, and arginine (see p. 18, lines 5-7) comprising the step of detecting ADMA (see Abstract). Balint & Cooke do not teach the step of "contacting the sample with an α-dicarbonyl compound."

However, Duerksen & Wilkinson teach the use of an α-dicarbonyl compound (see Abstract, "4-(Oxoacetyl)phenoxyacetic acid (OAPA)") as a linker for immobilizing arginine-containing compounds to solid phases (see p. 444, col. 1, "solid supports"). Therefore, it would have been obvious for a person of ordinary skill in the art to modify the method of detecting ADMA of Balint & Cooke with the use of OAPA because Duerksen & Wilkinson discovered that OAPA has the advantages of specificity, water solubility, negative charge, and linking ability (see Abstract).

With respect to claims 2 and 15-16, Duerksen & Wilkinson teach a method comprising phenylglyoxal (see Abstract, "4-(Oxoacetyl)phenoxyacetic acid (OAPA)") (see also, p. 450, col. 1, "phenylglyoxal").

With respect to claims 3-4 and 18, Balint & Cooke teach a method wherein α-amino groups are modified with a dye (see p. 20, line 6).

With respect to claims 5-7, Balint & Cooke teach a method comprising an antibody to ADMA (see p. 7, lines 18-20) that is detectaby labeled (see p. 16, lines 23-26).

With respect to claim 8, Balint & Cooke teach a method wherein HPLC is used (see p. 19, lines 27-28).

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Balint & Cooke (WO 98/49199) and Duerksen & Wilkinson, 160 ANAL. BIOCHEM. 444 (1987), as applied to claim 1, and further in view of Fishman et al. (US 5,318,680).

Balint & Cooke and Duerksen & Wilkinson teach a method of detecting ADMA in a sample as substantially described supra. The aforementioned references do not teach a method using capillary electrophoresis.

However, Fishman et al. teach the use of capillary electrophoresis for derivatizing and separating sample components (see Abstract). Therefore, it would have been obvious for a person of ordinary skill in the art to perform the method of detecting ADMA in a sample, as taught by Balint & Cooke and Duerksen & Wilkinson, with the use of capillary electrophoresis because Fishman et al. discovered that on-column derivatization results in fast kinetics and high yield (see Abstract).

Response to Arguments

In prior Office Action, claims 1-9 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Applicants' argumentation and/or amendments are sufficient to overcome these rejections. Accordingly, these rejections are withdrawn.

In prior Office Action, claims 1-8 were rejected under 35 U.S.C. 103(a) as being unpatentable over Balint & Cooke (WO 98/49199) in view of Duerksen & Wilkinson, 160 ANAL. BIOCHEM. 444 (1987). In response, Applicants argue that Balint & Cooke do not propose any modification of SDMA or arginine (see Applicants' reply, p. 8, lines 24-26), while Duerksen & Wilkinson do not discuss contacting a sample containing ADMA, SDMA, and arginine with an α-carbonyl compound (see Applicants' reply, p. 8, lines 29-31).

Applicants' arguments have been carefully considered but are not persuasive because one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicant's arguments do not appear to sufficiently show how the Applicants' claimed invention avoids the *combined* teachings of Balint & Cooke and Duerksen & Wilkinson. As such, it appears that the *combined* teachings of Balint & Cooke and Duerksen & Wilkinson teach each and every step of Applicants' invention, as claimed. As stated in the instant and prior Office Actions, Duerksen & Wilkinson provide motivation for combining the teachings of Balint & Cooke and Duerksen & Wilkinson because Duerksen & Wilkinson discovered that OAPA has the advantages of specificity, water solubility, negative charge, and linking ability (see Abstract).

Conclusion

No claims are allowed at this time.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David J Venci
Examiner

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

08/22/05